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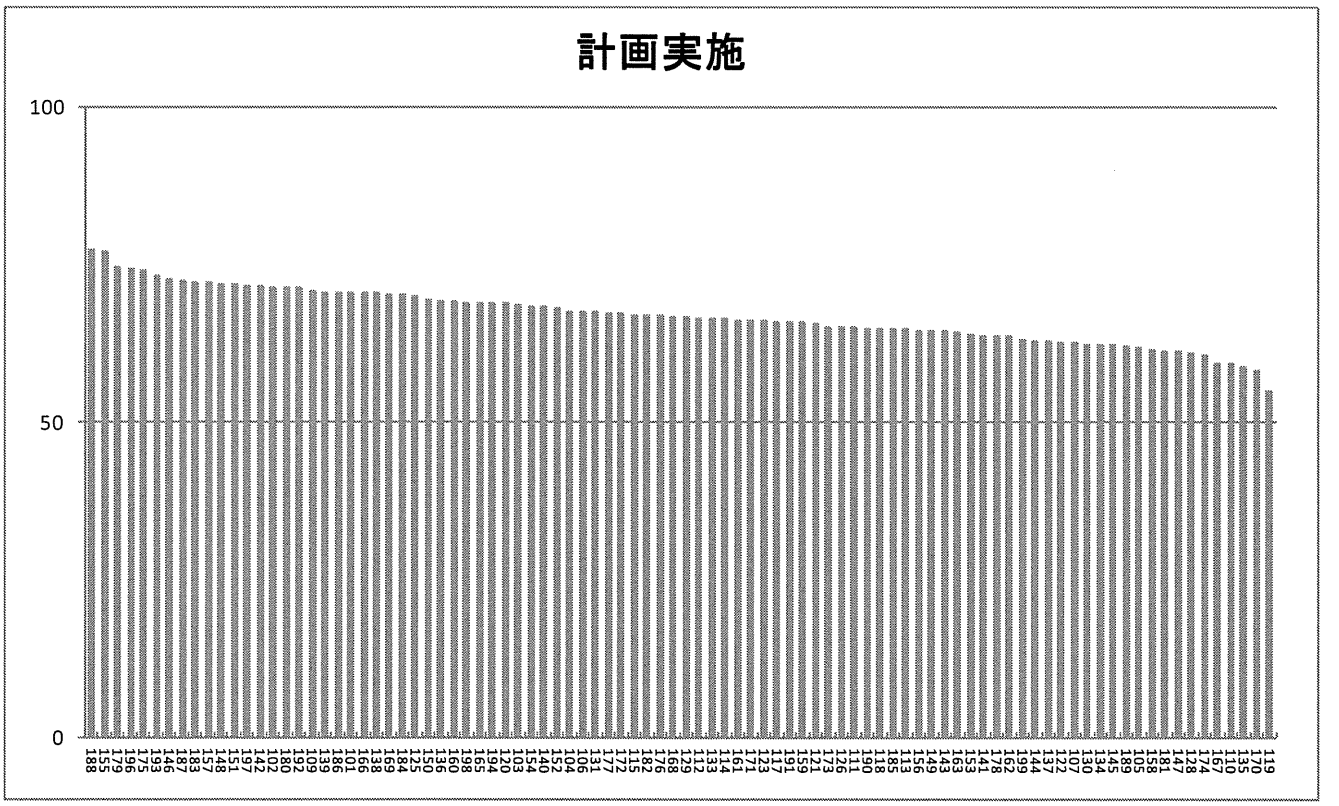
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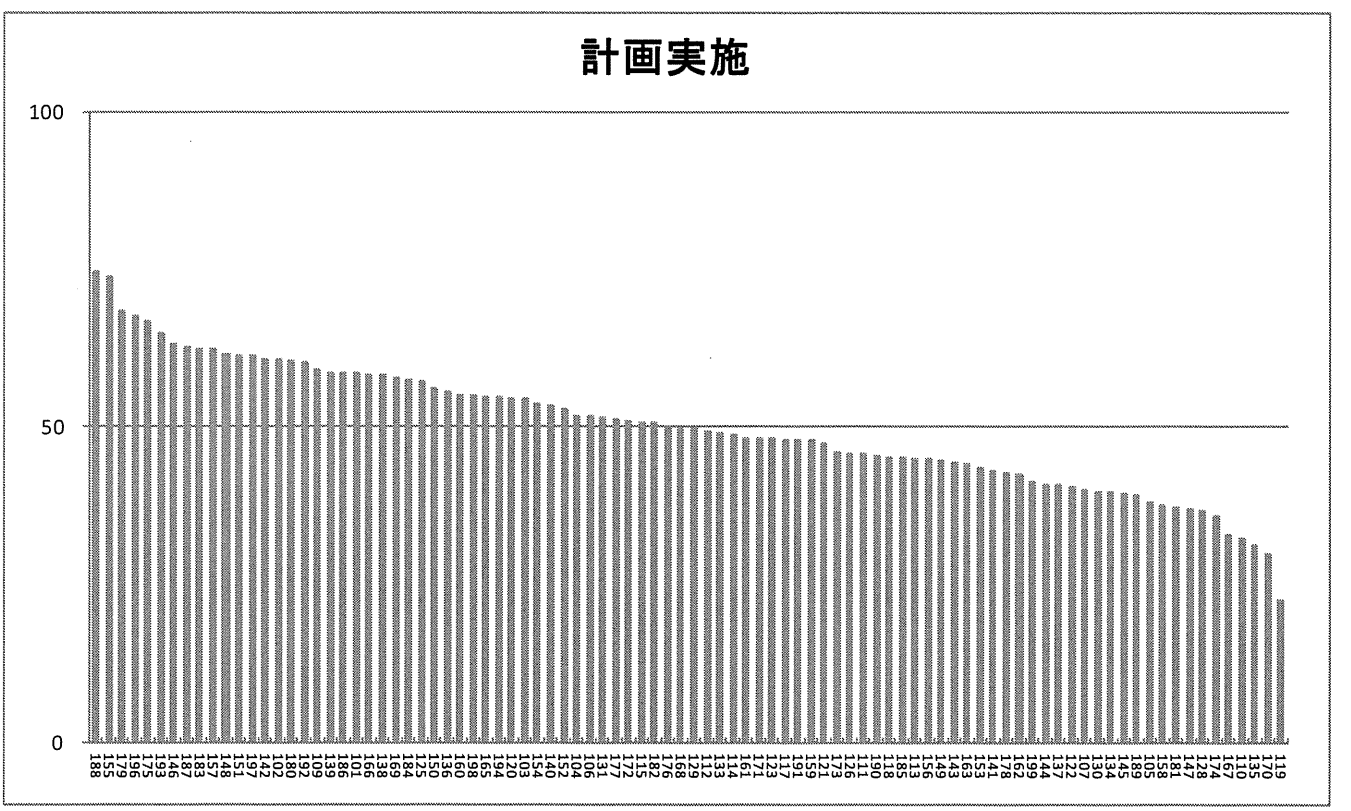
偏差値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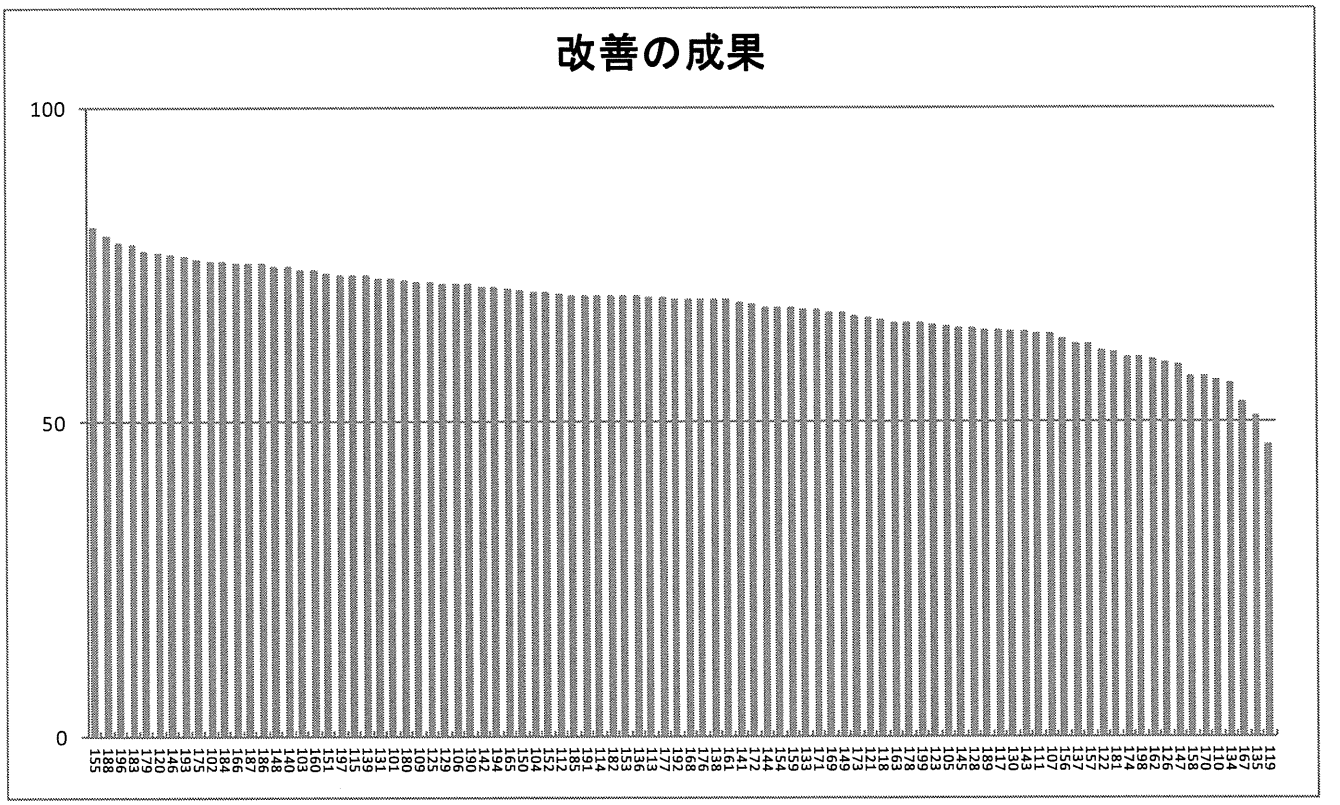
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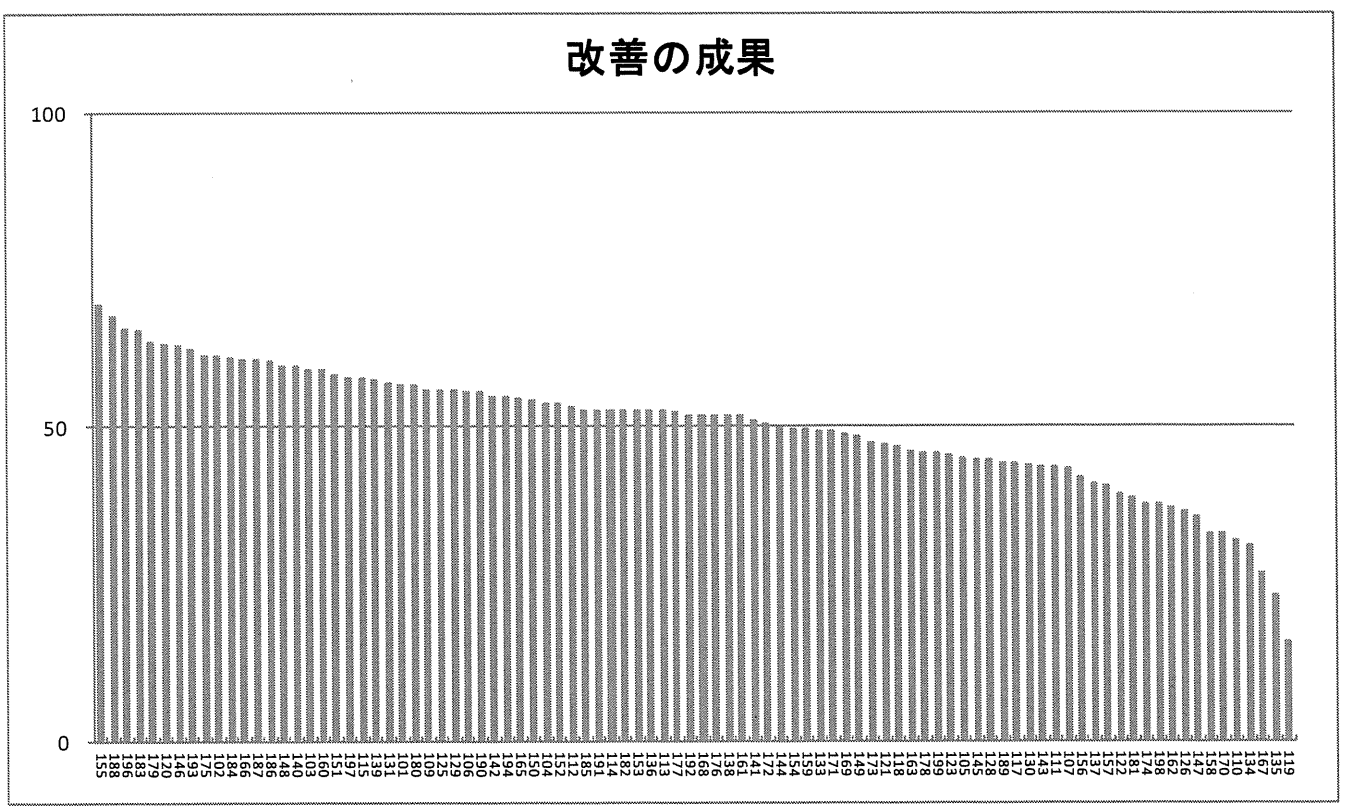
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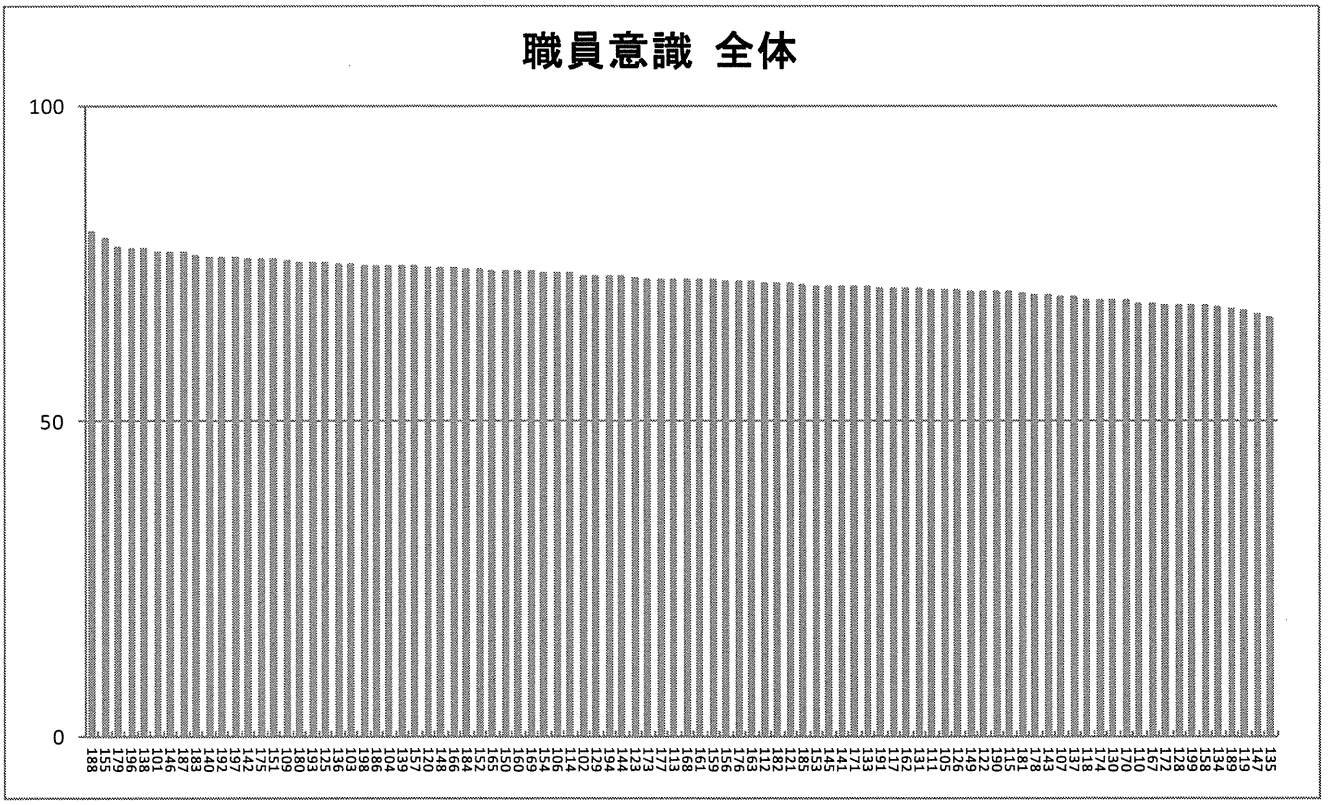
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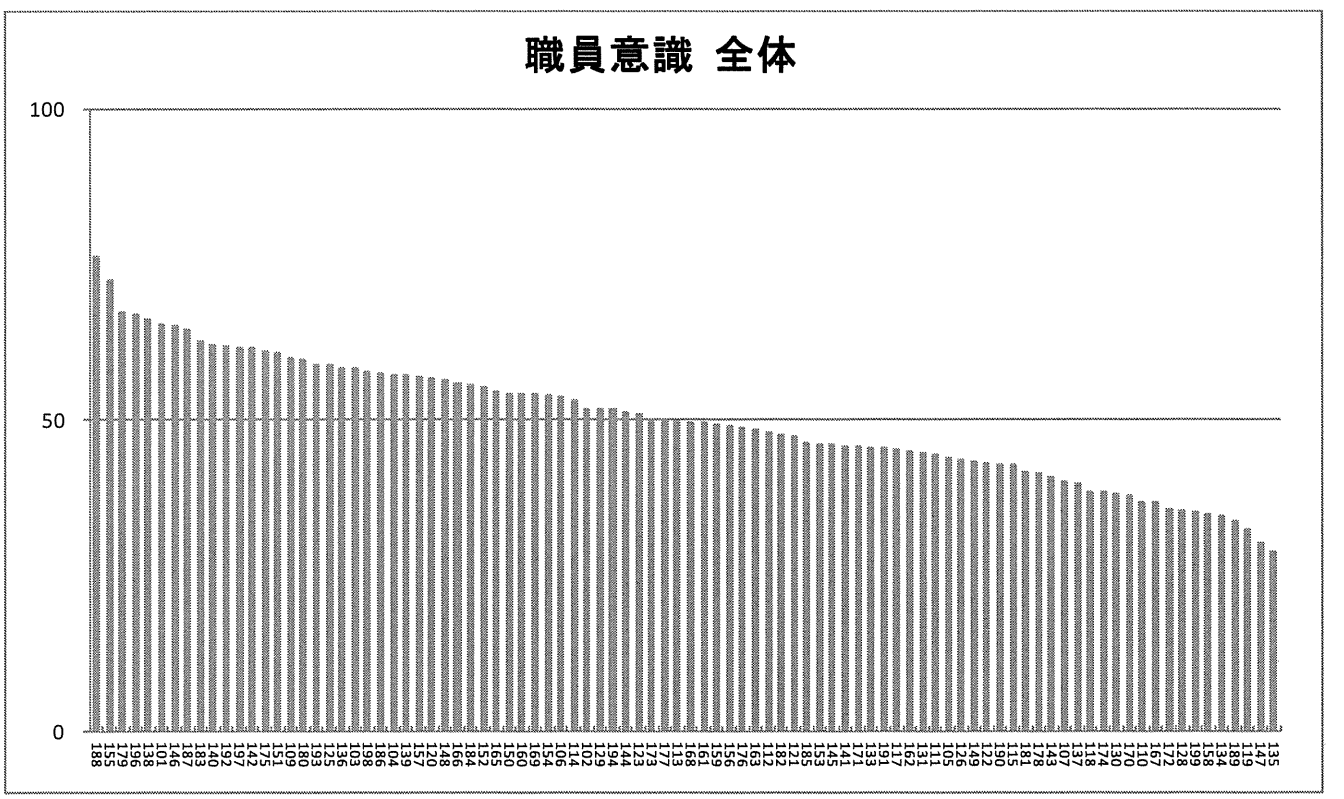
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臨床指標の公表に関する論点整理

	長所	短所
医療者	・診療を見直し、改善するきっかけになる。 ・より質の高い医療を行う職場を選択しうる。 ・レポートに対するネガティブな姿勢は時間と共に緩和される。	・消費者よりも臨床指標の公表に対して慎重であり、利用を最小限に留めようとする。 ・また逆に公表された臨床指標を疑い、信頼性を否定することもある。 ・公表のされ方によっては、専門職の独立性・自律性に公的な介入をされる感覚を持ちうる。
医療機関	・多くの場合、診療パフォーマンスが改善する。 ・病院の透明性や説明責任に対する要求に応えることができる。 ・病院間の比較が、診療の質改善の動機になる。 ・より良い設備や独自のサービスを導入するきっかけとなる。 ・取組みが病院の名声を高めることに繋がる。	・指標に表れる部分を、本当に必要な部分に優先して重要視する場合がある。 ・データの間違いやミスリーディングは病院に不当な損害を与えうる。 ・クリームスキミングを行う可能性がある。 ・臨床指標の公表にコストが必要である。
	・ 医療機関は公表された臨床指標を比較的よく利用し、反応する。 ・パフォーマンス指標が悪い医療機関ほど、データ自体やデータに基づいた行動の妥当性に、批判的である傾向あり。 ・しかし、批判的な病院も、公表データや内部データを使って質改善活動を行っている場合がある。	
医療消費者・患者	・指標を比較することで、より質の高い医療を提供する病院を選択しうる。 ・患者・消費者の情報利用が、病院の質改善への取り組みを促進させうる。	・必ずしも公表された臨床指標が患者の目を引くとは限らない。 ・また目に入ったとしてもそれらを理解し、信頼し、得た情報を病院の選択に用いることは少ない。 ・一部の利用者はネガティブな情報を利用して医療提供者を攻撃することがある。 ・利用される際に一部が過度に強調されて視野が狭くなることがある。
	・情報の利用度は、若い人、高等教育を受けた人で高い。	
政府・保険者	・質の高い医療が国民に提供されることで労働者の生産性が高まる。	
	・臨床指標の公表は、僅かながら保険者の行動に影響を与える。 ・詳細なパフォーマンス指標の比較データよりも、認証などの包括的な質の保証やコストにより大きな関心を向ける傾向がある。	
マスメディア	・人々の情報の利用・普及を促進する役割を果たしうる。	・メディアの特徴として、情報を過度に単純化し、センセーショナルに報道する傾向がある。
	・公表された臨床指標利用の先導的に利用しうる。	
全般	・重要であることよりも、測定しやすいことが優先されて指標が選択されることがある。	

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2010.10　京都大学医学研究科医療経済学分野

臨床指標の公表に関する議論

QIP ワークショップ「臨床指標の公表」その1：議論概要

2010 年 11 月 25 日

[開催概要]

- 日時:　2010 年 11 月 25 日（木） 13:00-15:00
- 場所:　京都大学吉田南キャンパス G 棟 2F セミナー室（A）
- 参加者:
  - QIP 参加病院
- スタッフ
  - 今中（説明）、猪飼（説明）、宇川（書記）、山下、田中、国澤、パク

[内容抄録]

¶ 挨拶と諸確認（今中）

- 会議参加者名簿の参加者への配布の確認
- 本課題への取り組み経緯と今後の流れ

¶ 臨床指標公表と今後公表予定の臨床指標の説明（猪飼）

¶ 総合討論

- 在院日数の出し方についての確認。

- 術中迅速病理診断について
  - 病理医は全国に 2000 人しかいない。人員確保しようと考えてもできないのに公表は適切なのか。
  - 地域性により改善が事実上困難な場合には、実名公表は望ましくないと考えている。
  - 術中病理迅速をした方がいい、例えば 5 年生存率がいいとかといったエビデンスはないのではないか。そういったものを CI として使うのは如何なものか。
  - 確かに病理医に関しては地域的な偏りはあるだろうし、診断についても重症度などは考慮していない。あくまで参考値として位置付けたり、実名公表はしないといった対策が考えられる。
  - 現実的に病理医を確保できないのだから公表はした方がいいと思うが、実名だと弊害があるのではないかと思う。

- AMI の説明について。
  - 説明に外来処方を含んでいないとあるが、一般の方々は理解できないと思うのでしっかりした注釈が必要ではないか。
  - 説明の強化で対応する。
  - こうした保険関係の細かいことは理解できないので、逆に書かない方がいいのではないか。また、実際データ自体の信頼性も下がっているのではないか。
  - こうした指標についてはこうした要因が大きい施設からは載せてくれとの要望もある。
  - 引き続き検討させてもらいたい。

- 中心静脈カテ関連敗血症の説明について
  - カテ連続日数の説明がわかりにくい。

- 術中迅速病理診断について。
  - 悪性腫瘍手術と迅速病理診断の適応がイコールではないのでは。
  - K コードなどの疑い病名など使えないか。
  - 特定の迅速診断が使われやすい疾患にしぼってはどうか。
  - 疑い病名が実際にどれほど使われているかがわからないという部分がある。
  - ICD と K コードの双方でチェックするというやり方はそうかもしれない。
  - 迅速診断が使われやすい疾患に絞るというのは確かにその方がいいかもしれない。

- HP 公表について
  - どういった人がどういった目的で HP を見に来るのか興味がある。Web 解析やアンケートなどでそういったデータを集めてくれればうれしい。
  - 簡便な形での調査という形で、ぜひ検討したい。
  - 今回の公表についての宣伝はどれほどしているのか。
  - 基本的には慎重にいきたいので宣伝はしていない。同じような試みをしているので病院団体とのやりとりはある。
  - 参加病院からのリンクはあるか。
  - 実例がある。参加病院側でぜひやってもらいたい。
  - 公表に同意した病院のデータの確認はしてるのか。データ確認の時間をとった方がよいのではないか。
  - これまでもそうだったが、今後も指標が追加される度にデータを送って個別指標の同意を確認してからの公表となる。

- その他
  - 他の病院団体とのからみはあるか。
  - 今は公表している指標や方法などで統一性がないので課題になっていくと思う。

  （CI の要望や病院名の略称、公表に関する広報への意見は出なかった）

- 患者満足度・職員意識調査の説明と質疑応答（今中）

以上

QIP ワークショップ「臨床指標の公表」その 2：議論概要

2010 年 11 月 27 日

2010 年 11 月 27 日（土）　10：30～12：30　京都大学東京オフィス

参加者：

QIP 参加病院関係者、スタッフ：今中（説明）、猪飼（説明）、田中、宇川、國澤（書記）

内容抄録

・資料に沿って、今中、猪飼より説明

指標 1）2）

→ 当院での高齢化が進んでおり、平均年齢や、標準偏差など付け加えられないか。グラフでなくとも、表の方などに。高齢者の割合など。

→ 指標の項目によっては付けているものもある。今後の検討課題の一つとする。

→ 資料自体はどのようなものを入手されているのか。退院処方以外の入院処方もわかるのか。

→ 様式 1 と EF ファイルを説明。

→ 転機は、死亡や短時間の入院も分母に含めているのか。

→ 短期間でも使われていると考えている処方なので含めている。

→ 木村先生が、βブロッカーの、心機能如何での比較トライアルを計画されている。日本人では必ずしも必要ない薬剤かもしれないが。

→ 今後、心機能によって層別化する必要があるかもしれない。

→ βブロッカー、ARB などは、両方とも使うことは少なく、どちらか一方だけとかでだしていないか。

→ 海外のガイドラインと日本のエビデンスとの相違は念頭に入れなくてはならない。いずれにせよ、どちらかというのは検討予定とする。

指標 6）

→ 選出コードはこれだけでよいか。

→ 脳梗塞後遺症などほかのコードは別にある。

→ なにか、このコードだけでは大雑把で不十分な気がする。急性期の他にもフラグができるとよいのではないか。エダラボン？や手術など。

→ 薬剤は、その使用頻度自体にばらつきがみられ頻度も低く、症例が少なくなる。絞り込みは難しい。

指標 7）

→ 開頭も含むのか。開頭はほとんどしない。穿頭のみがほとんど。穿頭だけでも良いと思う。

→ 亜急性になると、患者の状態がばらつき、患者の質が不均質と思える。

→ 検討課題とする。

指標 18）

→ 公表する意義がわからない。患者に公表する意味がない。

→ 率の高いところは保険病名では。施設ごとのチェックが必要。

→ T コードにカテーテル敗血症がある。それらを区別できないと、他の原因での敗血症を拾っている数値になるかもしれない。それらが混ざると、全体の信頼性が低下する。

→ DPC からの測定結果と、その他の結果との比較検討など、他の意見を受ける機会にもしたい。学会で発表する方がふさわしいのかもしれない。他に、公表することで、病名をつける作業の質が上がる可能性を期待したい。

指標 19）

→ 分母に悪性腫瘍以外を含んでいるの（外傷とか）のはおかしい。

→ 退院後に良悪がわかることがあり、データに反映されない。

→ たとえばがんセンターと一般病院では、様子が違って当然だろう

→ C コード、D(上皮内がん)、K で限定したほうがよいかもしれないので、検討する。

指標 20）

→ 緩和ケアはのぞいているのか。除かないと、地域のすべての死亡を引き受けているなどという病院もある。

→ むしろ、指標というよりは、このように、いろいろな病院がこの QIP に参加しているということを示す結果になっているように思える。

→ 4 日以上の根拠は？

→ 48 時間以上という既存の指標に合わせている。

指標 21、22）

→ 様式 1 の緊急入院は緊急入院加算がとれるもののみがそこに区分されているのではないか。

→ 2009 年は OK。2010 年 7 月から。定義表示を書き換える必要はあり。

指標 23）

→ 良いと思う。

全般）

→ 公表の意義として「認知される」とはどのような意味なのか。

→ 公表していることが、責任と自信、透明化など、対外的にポジティブなメッセージになる。

→ 現段階の項目はよいと思うが、今後増えるのであればそのたびにこのような検討が必要と思う。

→ 他のプロジェクトと比較して（もしくは混在していて）効率が悪いと思う。

→ 指標一つ一つに公表の承諾をもらっている。

→ それぞれのプロジェクトが異なる指標を異なる方法で出しているため、今後全体の調整が必要となることが予想される。年度内に他の団体との調整を検討したい。

→ 指標選択の基準は？出しやすさなどか。

→ 今回は、エビデンスが明確で、プロセスを扱い、改善が可能なもの、そして算出しやすいものを選択している。重要度はあまり考慮されていない。

→ 最終的には、死亡率とか合併症とか（アウトカム）を出すようになるのだろうが、逐一確認検討が必要である。また、公表している病院としていない病院が逆に目立ってしまうのではないか。

→ 目立つほど少なくないのが現状である。非公表とするデメリットは事実上ないと思われるが明確にはわからない。

→ アウトカム指標（合併症など）は、リスク調整などをしたいと思うのだが、調整は不十分性を内在しているので当面は実名公表にはふさわしくないと考えている。

→ アウトカムは匿名を基本として、フィードバック方法・出し方は、改善・改訂していきたい。

→ アウトカム指標など、一般人やマスコミなど本当はこちらが知りたいのだと思うのだが、数値に飛びつく傾向があるため、十分な説明も必要。

→ 実名公表のデメリットとして、批判や攻撃を受けたり、ガイドラインは従うべきものではないのに、裁判などが絡むと、ガイドラインに従っていない程度の低い病院という印象をうけたりするのか。

→ 批判や攻撃については海外も含め文献事例で問題視されていないようだが今後も留意していく。院内や患者への説明責任を果たしていく役割は大きくなると思われる。

→ グラフ（評価）のどのあたりの病院が同意しているのか。良いところだけとか、不均等になっていないか。

→ 全体的に分散していると思われるが、指標によって順位が違う。ある領域で低い値が

出ている病院も、公表に同意されている。また、限定的な公表同意も一部である。

→ 病院内での意見では、指標によって公表したりしなかったりを分けるのはよくなさそう。ただ、外科などは、抗生剤の使用方法の独自のポリシーがあるらしい。

→ 当院は都心だが、婦人科の撤退があって指標が出せない。もっと普遍的な疾患（誤嚥性肺炎など）を使用した指標がほしい。そして、層別化などもしてもらいたい。

→ QIP は層別化、リスク調整も従来より行ってきている。病院種別などもある。

→ 各項目を継続していくのか、新しい項目を作るのか。

→ 今後も継続するつもりである。指標は増やし、既存のものも改訂はするが、毎年同じ項目を出して経年に比較ができるようにしていきたい。それらの数値が改善されていることを示すのも目標の一つである。改訂された数値は、過去にさかのぼって再計算する。また、指標は順次増やしていく。

患者満足度等）

患者満足度・職員意識調査の説明と質疑応答

An outcome prediction model for adult intensive care

Takeshi Umegaki, Miho Sekimoto, Kenshi Hayashida and Yuichi Imanaka

ABSTRACT

Objective: To develop a prediction model of 28-day mortality in adult intensive care units using administrative data.

Design, setting and participants: We obtained data from 33 ICUs in Japan on all adult patients discharged from ICUs in 2007. Three predictive models were developed using (i) the five variables of the Critical Care Outcome Prediction Equation (COPE) model (age, unplanned admission, mechanical ventilation, hospital category and primary diagnosis) (the C model); (ii) 11 variables, including the COPE variables and six additional variables (sex, reason for ICU entry, time between hospital admission and ICU entry, use of fresh frozen plasma or a platelet preparation, dialysis, and use of pressors/vasoconstrictors (the P^+ model); and (iii) ten of the 11 variables, excluding primary diagnosis (the P^- model). Data for 6758 patients were stratified at the hospital level and randomly divided into test and validation datasets. Using the test dataset, five, 10 or nine variables were subjected to multiple logistic regression analysis (sex was excluded [$P > 0.05$]).

Main outcome measure: Mortality at 28 days after the first ICU day.

Results: Areas under the Receiver Operating Characteristic curve (AUROCs) for the test dataset in the C, P^+ and P^- models were 0.84, 0.89 and 0.87, respectively. Predicted mortality for the validation dataset gave Hosmer–Lemeshow χ^2 values of 12.91 ($P = 0.12$), 10.76 ($P = 0.22$) and 13.52 ($P = 0.1$), respectively, and AUROCs of 0.84, 0.89 and 0.90, respectively.

Conclusions: Our P^- model is robust and does not depend on disease identification. This is an advantage, as errors can arise in coding of primary diagnoses. Our model may facilitate mortality prediction based on administrative data collected on ICU patients.

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Concerns about quality of care and patient safety have increased the importance of monitoring of intensive care units in health care organisations. Performance measures for intensive care have been developed in response to increased demands to improve the quality of care.[1-3] Most studies have included mortality as an indicator of outcome, but mortality has varied between ICUs because of differences in the nature and severity of illness.[4-6] Several ICU risk-adjustment models[1] have been developed to compare mortality between institutions, including the Acute Physiology and Chronic Health Evaluation (APACHE) score, the Mortality Prediction Model (MPM), and the Simplified Acute Physiology Score (SAPS). Render and colleagues have proposed an automated ICU risk-adjustment tool.[7]

Severity scores have been constructed from demographics, physiological data and clinical diagnosis, and their validity has been confirmed in large-scale studies.[8-10] However, it is difficult to compare mortality rates between different ICUs based on the data available. Recently, the Critical Care Outcome Prediction Equation (COPE) model was proposed as a hospital mortality prediction model using administrative data. This model was constructed using five variables (age, unplanned admission, mechanical ventilation, hospital category and primary diagnosis). It showed that mortality could be well predicted from this model (area under the Receiver Operating Characteristic curve [AUROC] = 0.83–0.84).[11] Administrative data have the advantage of being available in a standardised format, which facilitates data collection from a large population and enables large-scale studies.

The Diagnosis Procedure Combination (DPC) system in Japan was introduced in 2004 and has become the standard method used in the health care financial system. Administrative data in this system include records of patient information and daily medical care. From these data, the types of all tests, medications and procedures and the use of intensive or special care and nursing services can be itemised on a daily basis. Procedures such as mechanical ventilation, renal replacement therapy and the use of vasoactive drugs are closely associated with mortality,[11-16] and their use varies somewhat among intensivists. Therefore, data on these interventions may help to predict mortality.

We used administrative data to develop three 28-day mortality prediction models based on:

- the five variables used in the COPE model (the C model);
- 11 variables: the five COPE model variables and six additional variables (sex, reason for ICU entry, time between hospital admission and ICU entry, use of fresh frozen plasma or a platelet preparation, dialysis, and use of pressors/vasoconstrictors) (the P^+ model); and

Table 1. Candidate variables used to develop the 28-day mortality prediction model

Type	Candidate variables	Category
Demographics	(1) Sex	Male; female
	(2) Age (years)	Continuous variable
Clinical factors	(3) Hospital admission	Scheduled;* emergency
	(4) Hospital category†	Metropolitan = 1; tertiary or regional = 0
	(5) Reason for entering ICU	After scheduled surgery;* after emergency surgery; internal medical disease
	(6) Primary diagnosis on admission	(See Table 2)
Any time during ICU admission	(7) Time between admission and ICU entry (days)	Direct; after 1 day; after 2–4 days;* after >4 days
	(8) Use of fresh frozen plasma or platelet preparation	Yes = 1; No = 0
	(9) Mechanical ventilation	Used ⩾ 5 hours; used < 5 hours; not used*
	(10) Dialysis	Yes = 1, No = 0
	(11) Pressor/vasoconstrictor	Yes = 1, No = 0

ICU = intensive care unit. * Reference value. † Hospital category for the present study was assumed to be metropolitan.

- ten of the 11 variables (excluding primary diagnosis) (the P^- model).

The aim of our study was to compare the predictive value of the P^- model with that of the models that included primary diagnosis as a variable.

Methods

Data sources and case selection criteria

All data for the study were extracted from the Quality Indicator/Improvement Project (QIP), which collects administrative data and analyses numerical indices of health care process outcomes in Japan. Of the hospitals that voluntarily participate in the QIP, we included 33 acute-care hospitals with ICUs, including surgical ICUs, medical ICUs, and surgical–medical ICUs. These hospitals were relatively large urban teaching hospitals, functioning in a similar manner in provision of cardiac surgery and neurosurgery. The database used in the analysis included all patients aged 20 years or over treated in an ICU at one of the 33 hospitals and discharged between 1 January and 31 December 2007. We were able to identify the time of ICU entry and the dates for the ICU stay based on specific codes in the administrative data. Patients with cardiovascular disease as a primary diagnosis (regardless of internal medical disease) and those who had undergone cardiovascular surgery were excluded from the study, as they were cared for primarily in cardiovascular care units. The data did not indicate whether a patient had been previously hospitalised in another ICU. However, as critical care patients are rarely transferred from one centre to another in Japan, we assumed that patients entering the ICU had not been transferred from another ICU.

Development of the prediction model and potential risk factors

Data for 6758 patients were stratified at the hospital level and randomly divided into test and validation datasets. Using the test dataset, five, 10 or nine variables were subjected to multiple logistic regression analysis (sex was excluded, as it was not significantly associated with mortality in the univariate analysis). Hospitals were stratified based on the number of beds, and hospitals were paired based on a similar number of beds. Test and validation datasets were established that contained similar numbers of hospitals, hospitals of similar sizes, and similar numbers of patients. The primary measure was defined as outcome 28 days after the first ICU day. A survivor who was discharged from hospital within 28 days was defined as a survivor at 28 days after the first ICU day. The mortality prediction model was constructed using the test dataset and evaluated using the validation dataset. Coefficients obtained from the test dataset were applied to cases in the validation dataset to calculate the predicted mortality.

Model development was based on up to 10 variables (Table 1), including the five variables in the COPE model.[11] Age was defined as a continuous variable. In defining the reason for ICU entry, patients who underwent surgery on the first ICU day or earlier were considered to be surgical patients. Among surgical patients, those who underwent surgery on the day of hospital admission or the following day were defined as "emergency" surgery cases, and those who did not have emergency surgery were defined as "scheduled" surgery cases. All other patients were considered to be internal medical patients. To define admission categories, items in the administrative data pertaining to the course of admission were used. The "emergency"

admission category indicates hospital admission after transport by ambulance or an unexpected admission. For the time between admission and ICU entry (in days), we referred to the Project IMPACT study.[7] As Japan is a comparatively small country and development of access to hospitals has occurred through medical care policy, the hospital category (as defined in the COPE model) was assumed to be metropolitan. As International classification of diseases, 10th revision (ICD-10) codes rather than ICD-10-AM (Australian modification) codes are used in Japan, we translated ICD-10-AM codes into their nearest equivalent ICD-10 codes (Table 2).

In addition to mechanical ventilation, which is included in the COPE model, dialysis, pressors/vasoconstrictors, and use of fresh frozen plasma or a platelet preparation were considered as life-support interventions. These factors have been found to be significantly associated with prognosis in ICU patients.[12-16] Patients having mechanical ventilation were defined as those requiring the procedure for 5 or more hours after ICU entry. These patients were identified from the corresponding codes. Because the data distinguished between continuous (≥ 5 hours) and temporary (< 5 hours) mechanical ventilation, the patients were divided into two categories. Non-invasive positive pressure ventilation was excluded. Dialysis included continuous renal replacement therapy, intermittent renal replacement therapy, plasma absorption, and plasma exchange, but excluded peritoneal dialysis, as this is rarely used for ICU patients. Pressors/vasoconstrictors included dopamine, dobutamine, noradrenaline (norepinephrine), adrenaline (epinephrine) and vasopressin, but the use of adrenaline in cardiopulmonary resuscitation was excluded. We were unable to identify whether dopamine was given as a renal dose or for cardiovascular support, but as we found no evidence that low-dose (renal-dose) dopamine was used,[17] we assumed that dopamine was used for cardiopulmonary support.

Relationships between individual variables and 28-day mortality were analysed by a χ^2 test using the test dataset. After exclusion of variables with $P > 0.25$, the remaining variables were subjected to multiple logistic regression analyses (stepwise backward selection method). The model was constructed using variables with $P < 0.05$, and the AUROC was calculated.

Prediction model performance

Calibration of the model was evaluated using the Hosmer–Lemeshow χ^2 test. A well calibrated model has a low χ^2 value (< 15.5; df = 8) and a high P value (> 0.05). The discrimination of the model was assessed by the AUROC, for which a value of > 0.80 is favourable.

Table 2. Translation of ICD-10-AM codes to ICD-10 codes in our study

Diagnostic category	ICD-10-AM codes	ICD-10 codes
Anaemia	D5	D5
Aplastic anaemia	D6	D60–61
Bacterial sepsis	A4	A4
Breast cancer	C5	C5
Cardiac arrest	I46	I46
Cardiac arrhythmias	I49	I47–49
Cardiac failure	I22–25	I50
CNS malignancy	C69–72	C69–72
COPD	J40–44	J40–44
Drug poisoning	T36–50	T36–50
Enteritis or colitis	K50–52	K50–52
Environmental disease	T66–79	T66–78
Epilepsy	G4	G40
Fluid and electrolyte disorders	E86–88	E86–88
Fungal sepsis	B30–49	B35–49
GIT investigation	R1	R1
Haemopoietic malignancy	C80–99	C81–96
Haemorrhagic shock	R57–58	R57–58
Head injury	S0	S0
Interstitial lung disease	J8	J8
Intracranial haemorrhage	I60–62	I60–62
Ischaemic bowel	K55	K55
Liver disease	K7	K7
Lower limb trauma	S7	S7
Lung malignancy	C3	C3
Malabsorption	K9	K90
Malignancy – other	D37–49	D37–48
Myocardial ischaemia	I20	I20–25
Other cerebrovascular disease	I65–69	I65–69
Other CNS disease	G9	G9
Other intestinal disease	K63	K63
Pancreatic cancer	C22–26	C25
Penetrating trauma	T15–19	T15–19
Pneumoconiosis	J60–79	J60–70
Pneumonia	J1	J12–18
Protozoal sepsis	B50–64	B50–64
Pulmonary vascular disease	I26–28	I26–28
Renal failure	N1	N17–19
Respiratory failure	J95–99	J96
Secondary malignancy	C76–79	C76–80
Stroke or CVA	I63–64	I63–64
Type 2 diabetes	E11	E11

CNS = central nervous system. COPD = chronic obstructive pulmonary disease. CVA = cerebrovascular accident. GIT = gastrointestinal. ICD-10 = International classification of diseases, 10th revision. ICD-10-AM = ICD-10 (Australian modification).

Table 3. Demographic data and primary diagnosis for the test and validation datasets

	Test dataset ($n=3505$)	Validation dataset ($n=253$)	P
Number of hospitals	16	17	
Type of hospital			
Teaching hospital	16	17	
University hospital	0	0	
Non-teaching hospital	0	0	
Hospital with provision of cardiac surgery	15	16	0.742
Hospital with provision of neurosurgery	15	16	0.742
Mean number of beds	541.7 (SD, 189.3)	566.7 (SD, 258.4)	0.768
Mean number of ICU beds	7.4 (SD, 4.5)	7.8 (SD, 2.7)	0.802
Mean number of admissions (per year)*	10 767.9 (SD, 5199.7)	118 16.0 (SD, 6937.5)	0.688
Mean number of ICU admissions (per year)*	512.3 (SD, 317.6)	543.2 (SD, 279.6)	0.807
Mean length of stay (days)	13.6 (SD, 1.8)	13.9 (SD, 1.8)	0.721
Mean length of ICU stay (days)	3.6 (SD, 4.8)	4.4 (SD, 7.4)	<0.001
Hospital mortality (%)	9.6%	13.7%	<0.001
28-day mortality (%)	7.4%	9.7%	<0.001
Primary diagnosis on admission	Frequency (%)	Frequency (%)	<0.001
Infection	6.4%	6.6%	
Toxin	1.2%	0.9%	
Neoplastic†	2.2%	4.2%	
Metabolic†	1.2%	0.6%	
Haematological and immunological	0.8%	0.8%	
Gastrointestinal†	2.9%	2.2%	
Renal	1.5%	1.4%	
Respiratory†	5.9%	6.4%	
Neuromuscular†	1.1%	2.8%	
Other internal medical disease	1.0%	1.1%	
Cerebral surgery†	11.6%	16.7%	
Abdominal surgery†	38.4%	30.6%	
Lung or mediastinal surgery†	9.2%	12.0%	
Orthopaedic surgery†	7.4%	5.2%	
Other surgery†	9.1%	8.5%	

ICU = intensive care unit. * Estimated values (per year) are shown because the information that the Quality Indicator/Improvement Project received from each facility covered the period from 1 January to 31 December or until 30 June. † Significant difference between the two datasets by χ^2 test.

Prediction model validation

The three models were validated as follows. Cross-validation was performed using the validation dataset to demonstrate that the prediction equation obtained from multiple logistic regression analyses of the test dataset had predictive validity. Predicted mortality for the validation dataset was calculated using the coefficients we had derived from the test dataset. The performance of the equation was tested using the Hosmer–Lemeshow χ^2 statistic and the AUROC (95% CI). In the P^- model, a contingency table for different cut-off points was obtained for the validation dataset. Predicted mortality for internal medical disease, emergency surgery, scheduled surgery and sepsis was also examined. All statistical analyses were performed using SPSS software, version 11.0J (SPSS Inc., Chicago, IL, USA).

Comparisons among the three models

The C, P^+ and P^- models were compared using the Hosmer–Lemeshow χ^2 test and the AUROC (95% CI).

Results

Demographic data are summarised in Table 3. Explanatory variables did not differ significantly between the two

Table 4. Frequency and mortality based on individual variables in the test dataset (univariate analysis) ($n = 3505$)

Variable	Frequency (%)	28-day mortality (%)	P*
(1) Sex			0.489
Male	56.3	8.2	
Female	43.7	7.2	
(2) Age (years)			< 0.001
20–44	9.8	3.1	
45–54	9.0	4.1	
55–64	18.8	5	
65–74	26.0	7	
⩾75	36.3	10.8	
(3) Admission category			< 0.001
Scheduled	48.8	1.5	
Emergency	51.2	12.9	
(5) Reason for entering ICU			< 0.001
After scheduled surgery	46.4	4.1	
After emergency surgery	29.4	5.9	
Medical disease	24.3	15.4	
(7) Time from admission to ICU entry			< 0.001
Direct	30.5	12.7	
After 1 day	18.2	3.4	
After 2–4 days	25.3	2.8	
After > 4 days	25.9	8.3	
(8) Use of fresh frozen plasma or platelet preparation			< 0.001
Yes	9.2	14.5	
No	90.8	6.6	
(9) Mechanical ventilation			< 0.001
Used ⩾ 5 hours	14.4	25.6	
Used < 5 hours	19.8	5.6	
Not used	65.8	3.0	
(10) Dialysis			< 0.001
Yes	3.7	32.8	
No	96.3	6.4	
(11) Pressors/vasoconstrictors			< 0.001
Yes	41.3	13.3	
No	58.7	3.2	

ICU = intensive care unit. * P value for 28-day mortality.

datasets, except for length of ICU stay and primary diagnosis. Abdominal surgery was the most common type of surgery among surgical patients in both datasets. In patients with medical conditions, the most common reason for hospitalisation was infection. Among surgical patients, rates of cerebral, abdominal, lung, mediastinal and orthopaedic surgery differed significantly between datasets, and similarly, among medical patients, rates of neoplastic, metabolic, gastrointestinal, respiratory and neuromuscular disease differed significantly.

The overall 28-day mortality was 8.5%. In the univariate analysis (Table 4), the strongest association with mortality was found for dialysis (32.8%), followed by mechanical ventilation (⩾ 5 hours) (25.6%). Sex was not significantly associated with mortality ($P = 0.489$). Variables other than sex were subjected to multiple logistic regression analysis.

Coefficients of the variables, odds ratios (ORs), and the final equation for the validation dataset are shown in Table 5. Factors associated with a high risk of death in the C, P^+ and P^- models were haemopoietic malignancy (OR, 23.07 [95% CI, 4.91–108.44]); stroke or cerebrovascular accident (OR, 20.34 [95% CI, 2.34–176.77]); and use of pressors/vasoconstrictors (OR, 7.12 [95% CI, 5.11–9.91]). Hosmer–Lemeshow χ^2 values, P values, and 95% confidence intervals for AUROC values are shown in Table 6. The P^- model showed good calibration for three of four diagnostic groups (being best for internal medical disease [$\chi^2 = 4.00$] and worst for sepsis [$\chi^2 = 17.38$]). We also identified different levels of probability in the validation dataset (Table 7). The discrimination ratio was 91.8% for 50% probability, and the AUROC was 0.87 for the test dataset and 0.90 for the validation dataset.

Discussion

The APACHE score, MPM and SAPS are widely used in intensive care medicine.[18-29] These approaches depend primarily on organ scores that require physiological data. Ohno-Machado and colleagues found that AUROCs for APACHE II, APACHE III, MPM_0 (MPM at admission), MPM_{24} (MPM at 24 hours), MPM II_0, MPM II_{24}, SAPS and SAPS II were all ⩾ 0.80 except for SAPS.[18]

In contrast to these models, Duke and colleagues[11] derived the COPE model using administrative data. This model is favoured because it can predict mortality with relatively few variables, and is currently the only model based on administrative data alone. The COPE model includes mechanical ventilation as intensive-care therapy but does not include other life-support interventions such as dialysis and pressors/vasoconstrictors. However, the Hosmer–Lemeshow χ^2 statistic suggested that calibration of the COPE model was no better than that of APACHE III.

Compared with the COPE model, the P^- model developed in our study is based on prediction of 28-day mortality, rather than hospital mortality, and may serve as a new tool for ICU evaluation based on administrative data. The P^- model also has several other advantages over existing models. First, the variables depend on information that can

Table 5. Coefficients in the C , P^+ , P^- models developed using the test dataset (multivariate analysis) ($n = 3505$)*

	C model		P^+ model		P^- model	
Variable	B	OR (95% CI)	B	OR (95% CI)	B	OR (95% CI)
(2) Age	0.03	1.03 (1.02–1.04)	0.04	1.04 (1.02–1.05)	0.03	1.03 (1.02–1.04)
(3) Admission category (emergency)	1.83	6.26 (4.05–9.67)	1.91	6.74 (4.11–11.08)	1.85	6.38 (3.96–10.30)
(5) Reason for ICU entry						
(i) After emergency surgery			1.02	2.78 (1.37–5.62)	1.06	2.90 (1.47–5.73)
(ii) Medical disease			1.25	3.51 (1.97–6.25)	1.20	3.31 (1.89–5.79)
(7) Time from admission to ICU entry						
(i) Direct			−1.34	0.26 (0.15–0.46)	−1.17	0.31 (0.18–0.54)
(ii) After 1 day			−1.59	0.20 (0.10–0.44)	−1.49	0.22 (0.11–0.47)
(8) Use of fresh frozen plasma or platelet preparation			0.47	1.60 (1.03–2.50)		
(9) Mechanical ventilation (≥ 5 hours)	1.66	5.28 (3.97–7.03)	1.53	4.61 (3.33–6.37)	1.56	4.77 (3.51–6.50)
(10) Dialysis			1.33	3.78 (2.31–6.17)	1.47	4.35 (2.72–6.95)
(11) Pressors/vasoconstrictors			2.07	7.91 (5.62–11.15)	1.96	7.12 (5.11–9.91)
(6) Primary diagnosis on admission						
Haemopoietic malignancy	3.14	23.07 (4.91–108.44)	3.00	20.14 (3.42–118.76)		
Other CNS disease	1.41	4.11 (0.95–17.87)	1.85	6.37 (1.33–30.43)		
Haemorrhagic shock			1.39	4.03 (1.47–11.05)		
Stroke or CVA	1.21	3.37 (1.30–8.73)	3.01	20.34 (2.34–176.78)		
Liver disease	2.01	7.46 (2.72–20.43)	2.08	8.00 (2.52–25.16)		
Intracranial haemorrhage			1.36	3.90 (1.73–8.79)		
Environmental disease	1.70	5.49 (1.33–22.60)	1.60	4.93 (1.13–21.48)		
Lower limb trauma	−2.29	0.10 (0.01–0.74)	−2.28	0.10 (0.01–0.78)		
Renal failure	0.73	2.07 (1.01–4.26)				
Pneumonia	0.64	1.90 (1.05–3.43)				
Constant	−6.14		−8.23		−7.67	

B = β coefficient. CNS = central nervous system. CVA = cerebrovascular accident. ICU = intensive care unit. OR = odds ratio.

* Predicted mortality risk = $e^y / (e^y + 1)$, where $y = [B_{(2)} \times (2)] + [B_{(3)} \times (3)] + [B_{(5\text{-i})} \times (5\text{-i})] + [B_{(5\text{-ii})} \times (5\text{-ii})] + [B_{(7\text{-i})} \times (7\text{-i})] + [B_{(7\text{-ii})} \times (7\text{-ii})] + [B_{(8)} \times (8)] + [B_{(9)} \times (9)] + [B_{(10)} \times (10)] + [B_{(11)} \times (11)] + [B_{(6)} \times (6)]$ + constant. Each of the values (3), (5-i), (5-ii), (7-i), (7-ii), (8), (9), (10), (11) and (6) is equal to 1 if the variable is applicable or 0 if the variable is not applicable.

Table 6. Validation of the prediction model

Dataset	Model	No. of patients	28-day mortality	Hosmer–Lemeshow χ^2	*P*	AUROC (95% CI)
Test	P^-	3505	7.4	14.49	0.07	0.87 (0.85–0.90)
Test	P^+	3505	7.4	5.36	0.72	0.89 (0.87–0.91)
Test	C	3505	7.4	20.41	0.01	0.84 (0.82–0.87)
Validation	P^-	3253	9.7	13.52	0.10	0.90 (0.88–0.92)
Validation	P^+	3253	9.7	10.76	0.22	0.89 (0.87–0.90)
Validation	C	3253	9.7	12.91	0.12	0.84 (0.82–0.86)
(Subgroup of validation dataset)						
Internal medical disease	P^-	877	21.7	4.00	0.86	0.85 (0.82–0.88)
Emergency surgery	P^-	854	7.6	14.95	0.06	0.91 (0.88–0.94)
Scheduled surgery	P^-	1522	4.1	11.55	0.17	0.85 (0.81–0.90)
Sepsis	P^-	264	36.0	17.38	0.03	0.82 (0.77–0.89)

Table 7. Contingency table for different levels of cut-off points in the validation dataset in the P⁻ model

Cut-off points			Expected: Survivors	Expected: Non-survivors	DR
20%	Observed	Survivor	2699	237	89.6%
		Non-survivor	100	217	
50%		Survivor	2874	62	91.8%
		Non-survivor	205	112	
70%		Survivor	2926	10	91.4%
		Non-survivor	269	48	

DR = discrimination ratio.

be obtained from administrative data. These variables can be input by doctors and nurses in a timely manner, rather than at or after discharge, which improves the reliability of the data. Moreover, the model uses only eight variables, which facilitates its generalisation and application. Second, the model is independent of the primary diagnosis, which avoids the difficulty of disease identification in critical care patients. Also, coding for primary diagnosis is the basis for reimbursement in the health care system, and this diagnosis may be important for determining illness severity. A disadvantage of this approach is the potential for coding errors, especially in ICU patients.[11]

The 2007 Project IMPACT study[30] used a combination of MPM II_0 to assess clinical performance and a new Weighted Hospital Days scale to assess resource utilisation for ICU benchmarking. Our QIP study and the Project IMPACT study had a similar element of uncertainty regarding the clinical course after discharge, as data collection is difficult after discharge.[31] Thus, although 90-day mortality rate may be a better measure of outcome than 28-day mortality, the latter measure is more accurate because patients are usually discharged after less than 90 days. The COPE model is also a good predictor of hospital mortality. For these reasons, we used 28-day mortality as the endpoint.

There are several limitations to our study. First, we did not compare our model with scoring systems using physiological data, as our data did not include severity scores. Thus we cannot determine whether the accuracy of the model is high or low compared with other systems. Second, the administrative data include information on a calendar-day basis rather than an hourly basis, and thus the first ICU day was defined by a calendar day. This meant we were unable to distinguish between the use of dialysis and pressors/vasoconstrictors before or after ICU entry on the first ICU day. However, these resources are mostly used under monitoring in the ICU. Third, the indications for mechanical ventilation, dialysis and pressors/vasoconstrictors varied among hospitals, which may have produced therapeutic bias. Fourth, the administrative data do not indicate whether renal replacement therapy was given for chronic or acute renal failure or for a non-renal indication; whether mechanical ventilation was used for acute respiratory failure or during the postoperative course; or whether pressors/vasoconstrictors were used to treat hypovolaemic or septic shock. Finally, different admission criteria among ICUs could have produced a selection bias that affected mortality. Our model has a therapeutic bias similar to that of the COPE model, including the use of mechanical ventilation, dialysis, pressors/vasoconstrictors, and the use of fresh frozen plasma or a platelet preparation. However, it is likely that there would have been appropriate selection of these therapies because of common knowledge of guidelines.

Among the variables, sex was not significantly associated with outcome, which is consistent with other scoring systems. Age is an important variable for all scoring systems, and the predictive value of the model can be increased by adding other variables.[31] The COPE model[11] has high discrimination, suggesting that the predictive ability of a model constructed from administrative data is high. The absence of physiological data in administrative data is a disadvantage, as diagnosis is not included in the P⁻ model, but our model has the advantage of using administrative data that is routinely collected on all patients. Comparison of the performance of ICUs is currently being attempted using administrative data, and our model establishes a method for evaluation of illness severity. However, as our study included 9% of hospitals that use the DPC system and did not include university hospitals and non-teaching hospitals, further verification and modification of the model is required in a larger sample of patients and ICUs.

Conclusion

The 28-day mortality prediction model for intensive care (the P⁻ model) proposed in our study is based solely on administrative data, is independent of primary diagnosis, and uses a relatively small number of variables that are easily collected. In addition to the COPE model, this model can be used to evaluate illness severity based on administrative data and may be applicable to critical care studies.

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Current anticoagulation therapy for sepsis-induced disseminated intravascular coagulation in Japan: results of a multicenter study using administrative data

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Abstract: Objective: Disseminated intravascular coagulation (DIC) is a serious complication associated with various underlying disorders, including sepsis. The aim of the current study was to investigate the status of therapy for patients with sepsis-induced DIC and to examine the association between 28-day mortality and use of anticoagulants. **Methods:** A multicenter cross-sectional study was performed from January 1, 2007 to December 31, 2008 in 45 ICUs in Japan. Using administrative data, 579 cases of sepsis-induced DIC were identified among patients who were admitted to an ICU, and these cases were used to assess the status of DIC therapy. The 28-day mortality was adjusted for the Critical care Outcome Prediction Equation (COPE) score, the Charlson comorbidity index and patient age, and associations with anticoagulants were then examined. **Results:** Protease inhibitors were used in 413 cases (71.3%), and antithrombin, unfractionated heparin, and low molecular weight heparin/danaparoid were used in 313 (54.1%), 385 (66.5%) and 201 (34.7%) cases, respectively. The overall 28-day mortality was 37%. In a Cox proportional hazards regression model, the hazard ratio (HR) of unfractionated heparin was 1.41, with a significant adverse effect on mortality ($P=0.02$). In a similar analysis, the HRs for protease inhibitors, antithrombin and low molecular weight heparin/danaparoid were 0.86, 0.90 and 0.88, respectively. These agents showed a tendency to reduce 28-day mortality, but the effect was not significant. **Conclusions:** A review of administrative data revealed that protease inhibitors were most frequently used in DIC anticoagulation therapy in ICUs in Japan. Unfractionated heparin was the only therapy to have a significant adverse effect on mortality.

Key words: ①disseminated intravascular coagulation, ②anticoagulants, ③multicenter study

Introduction

Disseminated intravascular coagulation (DIC) is a complex, acquired life-threatening disorder characterized by massive systemic intravascular coagulation that leads to widespread deposition of fibrin in the circulation [1]. Anticoagulation therapy has been suggested to be beneficial for DIC [2], and a study on guidelines for this therapy was published in 2007 in Japan [3]. The aims of the current retrospective study were to investigate the status of therapy for patients with sepsis-induced DIC in ICUs in Japan, and to evaluate the association between use of anticoagulants and 28-day mortality.

This article is featured in "HIGHLIGHTS IN THIS ISSUE". Please see the issue of J Jpn Soc Intensive Care Med 2010; 17: 474-476.

Methods

Cases and selection criteria

Data were obtained from the Quality Indicator/Improvement Project (QIP), in which detailed administrative claim data were collected from institutions. In the QIP, these data were analyzed to obtain numerical indices for the healthcare process, patient outcomes, and management efficiency to provide feedback to establishments that participate voluntarily in the project. In the current study, administrative data were surveyed from 45 acute care hospitals with an ICU. These data provided information on the characteristics of patients and daily medical care, thereby permitting collection of data for a large population. The following selection criteria were

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